PLEASE AMEND THIS APPLICATION AS FOLLOWS:

In the Claims:

Please cancel the following claims:
4, 14, 21, 22, 130, 131, 141, and 142.

Please amend the following claims as follows:

1. (ORIGINAL) A method for the treatment of immune-related or immune-mediated disorders or diseases in a mammalian subject in need of such treatment, by manipulating the NKT cell population of said subject, wherein manipulation of said NKT cell population results in modulation of the Th1/Th2 cell balance towards an inflammatory response, said modulation being mediated by different components, cells, tissues or organs of said subject or another subject.

2. (ORIGINAL) A method for the treatment of immune-related or immune-mediated disorders or diseases in a mammalian subject in need of such treatment, by manipulating the NKT cell population of said subject, wherein manipulation of said NKT cell population results in modulation of the Th1/Th2 cell balance towards an anti-inflammatory or pro-inflammatory response, said modulation being mediated by different components, cells, tissues or organs of said subject's or another subject's immune system.

3. (ORIGINAL) A method for the treatment of immune-related or immune-mediated disorders or diseases in a mammalian subject in need of such treatment, by manipulating the NKT cell population of said subject, wherein manipulation of said NKT cell population results in modulation of the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells, said modulation being mediated by different components, cells, tissues or organs of said subject's or another subject's immune system.

4. (CANCELED) The method of claim 1, 2 or 3, wherein said components comprise cellular immune reaction elements, humoral immune reaction elements and cytokines.

5. (ORIGINAL) The method of claim 3, wherein said manipulation is performed by depletion of said NKT cell population.

6. (ORIGINAL) The method of claim 3 for the treatment of immune-related or immune-mediated disorders or diseases in a mammalian subject, comprising the steps of:

a. obtaining NKT cells from said subject or another subject;
b. *ex vivo* educating the NKT cells obtained in step (a) such that the resulting educated NKT cells may modulate the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells; and
c. re-introducing to said subject the educated NKT cells obtained in step (b) which may modulate the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells, resulting in an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

7. (ORIGINAL) The method of claim 6, wherein said *ex vivo* education of step (b) is performed by culturing said NKT cells in the presence of any one of:

a. antigens or epitopes associated with said immune-related or immune-mediated disorder or disease to be treated, antigens or epitopes associated with the immune-mediated inflammatory response, or any combination thereof;
b. at least one liver-associated cell of tolerized or non-tolerized subjects suffering from said immune-related or immune-mediated disorder or of said subject;
c. at least one cytokine or adhesion molecule, or any combination thereof; and
d. a combination of any of (a), (b) and (c).

8. (ORIGINAL) The method of claim 7 wherein said *ex vivo* education is performed by culturing said NKT cells in the presence of antigens associated with said immune-related or immune-mediated disorder or disease.

9. (ORIGINAL) The method of claim 8, wherein said antigens comprise allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated disorder or disease, xenogenic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

10. (ORIGINAL) The method of claim 7, wherein said liver-associated cells comprise Kupffer cells, Stellate cells, liver endothelial cells, liver-associated stem cells, an apolipoprotein, or any other liver-related lymphocytes.

11. (ORIGINAL) The method of claim 7, wherein said cytokines comprise IL4, IL10, TGFβ, IFNγ, IL12, IL2, IL18 or IL15.

12. (ORIGINAL) The method of claim 7, wherein said adhesion molecules comprise Integrins, Selectins or ICAMs.

13. (ORIGINAL) The method of claim 6, wherein said educated NKT cells are re-introduced to said subject by adoptive transfer.

14. (CANCELED) The method of claim 6 or 7, further comprising the step of eliciting in said subject immune modulation of said immune-related or immune-mediated disorder or disease by administering to said subject components, cells, tissues and/or organs derived from any allogeneic donor suffering from said immune-related or immune-mediated disorder, xenogeneic sources, syngeneic sources, autologous sources, non-autologous sources, immunologically functional equivalents, or any combination thereof.

15. (ORIGINAL) The method of claim 14, wherein said components, cells, tissues or organs are administered orally.

16. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject in need of such treatment by eliciting in said subject up or down regulation of the immune response to said disorder or disease by oral tolerization.

17. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject in need of such treatment by immune modulation through oral tolerance induction or oral immune regulation.

18. (ORIGINAL) The method of claim 17 wherein said immune modulation through oral tolerance induction or oral immune regulation involves the oral administration of liver extract.

19. (ORIGINAL) The method of claim 14 wherein said method of administration comprises oral, intravenous, parenteral, transdermal, subcutaneous, intravaginal, intraperitoneal, intranasal, mucosal, sublingual, topical or rectal administration, or any combination thereof.

20. (ORIGINAL) The method of claim 17 wherein said immune modulation through oral tolerance induction or oral immune regulation involves the oral administration of material comprising components, cells, tissues and/or organs derived from any allogeneic donor suffering from said immune-related or immune-mediated disorder or disease, xenogeneic sources, syngeneic sources, autologous sources, non-autologous sources, immunologically functional equivalents, or any combination thereof.

21. (CANCELED) The method of claim 6 or 7 further comprising eliciting in said subject up or down regulation of the immune response to said disorder or disease by oral tolerization, oral tolerance induction or oral immune regulation.

22. (CANCELED) The method of claim 6 or 7 further comprising immune modulation through oral tolerance induction or oral immune regulation.

23. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease comprising Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis, in a mammalian subject in need of such treatment by immune modulation through oral tolerance induction or oral immune regulation wherein the Th1/Th2 balance shifts towards Th2, the anti-inflammatory response, resulting in an increase of the $CD4^+$ $IL4^+$ $IL10^+/CD4^+$ IFNγ ratio.

24. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease comprising Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis in a mammalian subject in need of such treatment by the modulation of NKT cells wherein the Th1/Th2 balance shifts towards Th2, an anti-inflammatory response, resulting in an increase of the $CD4^+$ $IL4^+$ $IL10^+/CD4^+$ IFNγ ratio.

25. (ORIGINAL) The method of any one of claims 1 to 24, wherein said immune-related or immune-mediated disorder or disease is Non-Alcoholic Steatohepatitis.

26. (ORIGINAL) The method of any one of claims 1 to 24, wherein said immune-related or immune-mediated disorder or disease is diabetes mellitus or glucose intolerance.

27. (ORIGINAL) The method of any one of claims 1 to 24, wherein said immune-related or immune-mediated disorder or disease is obesity.

28. (ORIGINAL) The method of any one of claims 1 to 24, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

29. (ORIGINAL) The method of any one of claims 1 to 24, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

30. (ORIGINAL) The method according to any one of claims 1 to 24, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

31. (ORIGINAL) The method of any one of claims 25-30, wherein said mammalian subject is a human patient.

32. (ORIGINAL) The method of claim 6 or 7, wherein said NKT cells are NKT cells expressing the CD56 marker.

33. (ORIGINAL) A therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject, said composition comprising, as an effective ingredient, *ex vivo* educated xenogeneic, syngeneic, autologous or non-autologous NKT cells capable of modulating the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells, and optionally further comprising pharmaceutically acceptable carrier, diluent, excipient and/or additive.

34. (ORIGINAL) The therapeutic composition of claim 33, wherein said educated NKT cells mediate an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

35. (ORIGINAL) The therapeutic composition according to claim 34, wherein said educated NKT cells are obtained by *ex vivo* culturing in the presence of any one of:

a. antigens or epitopes associated with said immune-related or immune-mediated disorder or disease to be treated, antigens or epitopes associated with the immune-mediated inflammatory response, or any combination thereof;
b. at least one liver-associated cell of tolerized or non-tolerized patients suffering from said disorder or disease of said subject;
c. at least one cytokine, or adhesion molecule, or any combination thereof; and
d. a combination of any of (a), (b), (c) above.

36. (ORIGINAL) The therapeutic composition of claim 35, wherein said educated NKT cell is obtained by *ex vivo* culturing in the presence of antigens associated with said immune-related or immune-mediated disorder.

37. (ORIGINAL) The therapeutic composition of claim 36, wherein said antigens comprise allogeneic antigens from donors suffering from said immune-related or immune-mediated disorder or disease, xenogeneic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

38. (ORIGINAL) The therapeutic composition of claim 35, wherein said liver-associated cells comprise Kupffer cells, Stellate cells, liver endothelial cells and any other liver-related lymphocytes.

39. (ORIGINAL) The therapeutic composition of claim 35, wherein said cytokines comprise IL4, IL10, TGFβ, IFNγ, IL2, IL18, IL12 or IL15.

40. (ORIGINAL) The therapeutic composition of claim 35, wherein said adhesion molecules comprise Integrins, Selectin or ICAM.

41. (ORIGINAL) A therapeutic composition of any one of claims 33 to 40, wherein said immune-related or immune-mediated disorder or disease is Non-Alcoholic Steatohepatitis.

42. (ORIGINAL) The therapeutic composition of any one of claims 33 to 40, wherein said immune-related or immune-mediated disorder or disease is diabetes mellitus or glucose intolerance.

43. (ORIGINAL) The therapeutic composition of any one of claims 33 to 40, wherein said immune-related or immune-mediated disorder or disease is obesity.

44. (ORIGINAL) The therapeutic composition of any one of claims 33 to 40, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

45. (ORIGINAL) The therapeutic composition of any one of claims 33 to 40, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

46. (ORIGINAL) The therapeutic composition of any one of claims 33 to 40, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

47. (CANCELED) The use of an educated autologous, xenogeneic, syngeneic or non-autologous NKT cell in the manufacture of a therapeutic composition for modulating the

Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells, in a mammalian subject suffering of an immune-related or immune-mediated disorder or disease.

48. (CANCELED) The use of an educated autologous, xenogeneic, syngeneic or non-autologous NKT cell in the manufacture of a therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject, wherein educated NKT cells modulate the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells.

49. (CANCELED) The use of claim 47 or 48, wherein said educated NKT cells mediate an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

50. (ORIGINAL) The therapeutic composition of any one of claims 33 to 40 wherein the educated NKT cells of said composition modulate the Th1/Th2 cell balance towards anti-inflammatory cytokine producing cells in a mammalian subject suffering an immune-related or immune-mediated disorder or disease, and said NKT cells mediate an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

51. (ORIGINAL) The therapeutic composition of any one of claims 33 to 40 for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject, wherein the educated NKT cells of said composition modulate the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells.

52. (ORIGINAL) An *ex vivo* educated autologous, syngeneic, xenogeneic or non-autologous NKT cell for use in the treatment of immune-related or immune-mediated disorders or disease in a mammalian subject in need of such treatment.

53. (ORIGINAL) The educated NKT cell of claim 52, wherein said educated NKT cell has been *ex vivo* cultured in the presence of any one of:

a. antigens or epitopes associated with said immune-related or immune-mediated disorder or disease to be treated, antigens or epitopes associated with the immune-mediated inflammatory response, or any combination thereof;
b. at least one liver-associated cell of tolerized or non-tolerized patients suffering from said immune-related or immune-mediated disorder or disease or of said subject;
c. at least one cytokine, or adhesion molecule or any combination thereof; and
d. a combination of any of (a), (b) and (c) above.

54. (ORIGINAL) The educated NKT cell of claim 53, wherein said antigens comprise allogeneic antigens of donors suffering from said immune-related or immune-mediated disorder or disease, xenogeneic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combinations thereof.

55. (ORIGINAL) The educated NKT cell of claim 53, wherein said liver-associated cells comprise Kupffer cells, Stellate cells, liver endothelial cells or any other liver-related lymphocytes.

56. (ORIGINAL) The educated NKT cell of claim 53, wherein said cytokines comprise IL4, IL10, TGFβ, IFNγ, IL2, IL18, IL12 or IL15.

57. (ORIGINAL) The educated NKT cell of claim 53, wherein said adhesion molecules comprise Integrins, Selectin or ICAMs.

58. (ORIGINAL) The educated NKT cell of any one of claims 52 to 57, wherein said immune-related or immune-mediated disorder or disease is Non-Alcoholic Steatohepatitis.

59. (ORIGINAL) The educated NKT cell of any one of claims 52 to 57, wherein said immune-related or immune-mediated disorder or disease is diabetes mellitus or glucose intolerance.

60. (ORIGINAL) The educated NKT cell of any one of claims 52 to 57, wherein said immune-related or immune-mediated disorder or disease is obesity.

61. (ORIGINAL) The educated NKT cell of any one of claims 52 to 57, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

62. (ORIGINAL) The educated NKT cell of any one of claims 52 to 57, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

63. (ORIGINAL) The educated NKT cell of any one of claims 52 to 57, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

64. (CANCELED) The use of an *ex vivo* educated autologous, syngeneic, xenogeneic or non-autologous NKT cell in the treatment of immune-related or immune-mediated disorders or disease in a mammalian subject in need of such treatment.

65. (CANCELED) The use of claim 64, wherein said educated NKT cell is according to any one of claims 53 to 57.

66. (ORIGINAL) A therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease, which composition comprises as an effective ingredient an antibody that specifically recognizes NKT cells.

67. (ORIGINAL) The therapeutic composition of claim 66, wherein said immune-related or immune-mediated disorder or disease is Non-Alcoholic Steatohepatitis.

68. (ORIGINAL) The therapeutic composition of claim 66, wherein said immune-related or immune-mediated disorder or disease is diabetes mellitus or glucose intolerance.

69. (ORIGINAL) The therapeutic composition of claim 66, wherein said immune-related or immune-mediated disorder or disease is obesity.

70. (ORIGINAL) The therapeutic composition of claim 66, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

71. (ORIGINAL) The therapeutic composition of claim 66, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

72. (ORIGINAL) The therapeutic composition of claim 66, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

73. (CANCELED) The use of an antibody that specifically recognizes the NKT cells, in the manufacture of a therapeutic composition for the manipulation of the NKT cells population in a mammalian subject suffering from an immune-related or immune-mediated disorder or disease.

74. (CANCELED) The use of claim 73, wherein said manipulation is the depletion of said NKT cell population.

75. (CANCELED) The use of claim 74, wherein depletion of said NKT cells population results in modulating the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells.

76. (CANCELED) The use of an antibody that specifically recognizes NKT cells, in the manufacture of a therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject.

77. (CANCELED) The use of any one of claims 73 to 76, wherein said immune related disorder or disease is Non-Alcoholic Steatohepatitis.

78. (CANCELED) The use of any one of claims 73 to 76, wherein said immune related disorder or disease is diabetes mellitus or glucose intolerance.

79. (CANCELED) The use of any one of claims 73 to 76, wherein said immune-related or immune-mediated disorder or disease is obesity.

80. (CANCELED) The use of any one of claims 73 to 76, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

81. (CANCELED) The use of any one of claims 73 to 76, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

82. (CANCELED) The use of any one of claims 73 to 76, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

83. (ORIGINAL) A method for the treatment of immune-related or immune-mediated disorders in a mammalian subject in need of such treatment, by manipulating NKT cell population of said subject, wherein manipulation of said NKT cell population results in modulation of the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells, said modulation being mediated by different components, cells, tissues or organs of said subject's or another subject's immune system.

84. (ORIGINAL) The method of claim 83, wherein said components comprise cellular immune reaction elements, humoral immune reaction elements and cytokines.

85. (ORIGINAL) The method of claim 83, wherein said manipulation is performed by depletion of said NKT cell population.

86. (ORIGINAL) The method of claim 83 for the treatment of immune-related or immune-mediated disorders in a mammalian subject comprising the steps of:

a. obtaining NKT cells from said subject or another subject ;
b. *ex vivo* educating the NKT cells obtained in step (a) such that the resulting educated NKT cells may modulate the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells; and
c. re-introducing to said subject the educated NKT cells obtained in step (b) which may modulate the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells, resulting in a decrease in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

87. (ORIGINAL) The method of claim 86, wherein said *ex vivo* education of step (b) is performed by culturing said NKT cells in the presence of any one of:

a. antigens or epitopes associated with the immune-related or immune-mediated disorder to be treated, antigens or epitopes associated with the immune-mediated inflammatory response, or any combination thereof;

b. at least one liver-associated cell of tolerized or non-tolerized subjects suffering from said immune-related or immune-mediated disorder or of said subject;
c. at least one cytokine, or adhesion molecule or any combination thereof; and
d. a combination of any of (a), (b) and (c).

88. (ORIGINAL) The method of claim 87 wherein said *ex vivo* education is performed by culturing said NKT cells in the presence of antigens associated with said immune-related or immune-mediated disorder.

89. (ORIGINAL) The method of claim 88, wherein said antigens comprise allogeneic antigens obtained from a donor subject suffering from said immune-related or immune-mediated disorders, xenogenic antigens, autologous antigens or recombinantly prepared antigens, or any combination thereof.

90. (ORIGINAL) The method of claim 85, wherein said liver-associated cells are selected from the group consisting of Kupffer cells, Stellate cells, liver endothelial cells, liver-associated stem cells and any other liver-related lymphocytes.

91. (ORIGINAL) The method of claim 87, wherein said cytokines comprise of IL4, IL10, TGFβ, IFNγ, IL12, IL2, IL18 or IL15.

92. (ORIGINAL) The method of claim 87, wherein said adhesion molecules comprise Integrins, Selectin or ICAM.

93. (ORIGINAL) The method of claim 86, wherein said educated NKT cells are re-introduced to said subject by adoptive transfer.

94. (ORIGINAL) The method of claim 86 or 87, further comprising the step of eliciting in said subject immune modulation of the immune-related or immune-mediated disorder by administering to said subject components, cells, tissues and/or organs derived

from any allogeneic donor suffering from said immune-related or immune-mediated disorder, xenogeneic sources, autologous sources, or immunologically functional equivalents, or any combination thereof.

95. (ORIGINAL) The method of claim 94, wherein said components, cells, tissues or organs are administered orally.

96. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject in need of such treatment by eliciting in said subject up or down regulation of the immune response to said disorder or disease by oral tolerization.

97. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject in need of such treatment by immune modulation through oral tolerance induction or oral immune regulation.

98. (ORIGINAL) The method of claim 97 wherein said immune modulation through oral tolerance induction or oral immune regulation involves the oral administration of liver extract.

99. (ORIGINAL) The method of claim 94 wherein said method of administration comprises oral, intravenous, parenteral, transdermal, subcutaneous, intravaginal, intraperitoneal, intranasal, mucosal, sublingual, topical or rectal administration, or any combination thereof.

100. (ORIGINAL) The method of claim 97 wherein said immune modulation through oral tolerance induction or oral immune regulation involves the oral administration of material comprising components, cells, tissues and/or organs derived from any allogeneic donor suffering from said immune-related or immune-mediated disorder or disease,

xenogeneic sources, syngeneic sources, autologous sources, non-autologous sources, immunologically functional equivalents, or any combination thereof.

101. (ORIGINAL) The method of claim 86 or 87 further comprising eliciting in said subject up or down regulation of the immune response to said disorder or disease by oral tolerization, oral tolerance induction or oral immune regulation.

102. (ORIGINAL) The method of claim 86 or 87 further comprising immune modulation through oral tolerance induction or oral immune regulation.

103. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease comprising Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis, in a mammalian subject in need of such treatment by immune modulation through oral tolerance induction or oral immune regulation wherein the Th1/Th2 balance shifts towards Th1, the pro-inflammatory response, resulting in a decrease of the $CD4^+$ $IL4^+$ $IL10^+/CD4^+$ IFNγ ratio.

104. (ORIGINAL) A method for the treatment of an immune-related or immune-mediated disorder or disease comprising Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis in a mammalian subject in need of such treatment by the modulation of NKT cells wherein the Th1/Th2 balance shifts towards Th1, a pro-inflammatory response, resulting in a decrease of the $CD4^+$ $IL4^+$ $IL10^+/CD4^+$ IFNγ ratio.

105. (ORIGINAL) The method of any one of claims 83 to 104, wherein said immune-related or immune-mediated disorder or disease is Non-Alcoholic Steatohepatitis.

106. (ORIGINAL) The method of any one of claims 83 to 104, wherein said immune-related or immune-mediated disorder or disease is diabetes mellitus or glucose intolerance.

107. (ORIGINAL) The method of any one of claims 83 to 104, wherein said immune-related or immune-mediated disorder or disease is obesity.

108. (ORIGINAL) The method of any one of claims 83 to 104, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

109. (ORIGINAL) The method of any one of claims 83 to 104, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

110. (ORIGINAL) The method according to any one of claims 83 to 104, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

111. (ORIGINAL) The method of any one of claims 105-110, wherein said mammalian subject is a human patient.

112. (ORIGINAL) The method of claim 86 or 87, wherein said NKT cells are NKT cells expressing the CD56 marker.

113. (ORIGINAL) A therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject, said composition comprising, as an effective ingredient, *ex vivo* educated xenogeneic, syngeneic, autologous or non-autologous NKT cells capable of modulating the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells, and optionally further comprising pharmaceutically acceptable carrier, diluent, excipient and/or additive.

114. (ORIGINAL) The therapeutic composition of claim 113, wherein said educated NKT cells mediate a decrease in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

115. (ORIGINAL) The therapeutic composition according to claim 114, wherein said educated NKT cells are obtained by *ex vivo* culturing in the presence of any one of:

a. antigens or epitopes associated with said immune-related or immune-mediated disorder or disease to be treated, antigens or epitopes associated with the immune-mediated inflammatory response, or any combination thereof;
b. at least one liver-associated cell of tolerized or non-tolerized patients suffering from said disorder or disease of said subject;
c. at least one cytokine, or adhesion molecule, or any combination thereof; and
d. a combination of any of (a), (b), (c) above.

116. (ORIGINAL) The therapeutic composition of claim 115, wherein said educated NKT cell is obtained by *ex vivo* culturing in the presence of antigens associated with said immune-related or immune-mediated disorder.

117. (ORIGINAL) The therapeutic composition of claim 116, wherein said antigens comprise allogeneic antigens from donors suffering from said immune-related or immune-mediated disorder or disease, xenogeneic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

118. (ORIGINAL) The therapeutic composition of claim 115, wherein said liver-associated cells comprise Kupffer cells, Stellate cells, liver endothelial cells and any other liver-related lymphocytes.

119. (ORIGINAL) The therapeutic composition of claim 115, wherein said cytokines comprise IL4, IL10, TGFβ, IFNγ, IL2, IL18, IL12 or IL15.

120. (ORIGINAL) The therapeutic composition of claim 115, wherein said adhesion molecules comprise Integrins, Selectin or ICAM.

121. (ORIGINAL) A therapeutic composition of any one of claims 113 to 120, wherein said immune-related or immune-mediated disorder or disease is Non-Alcoholic Steatohepatitis.

122. (ORIGINAL) The therapeutic composition of any one of claims 113 to 120, wherein said immune-related or immune-mediated disorder or disease is diabetes mellitus or glucose intolerance.

123. (ORIGINAL) The therapeutic composition of any one of claims 113 to 120, wherein said immune-related or immune-mediated disorder or disease is obesity.

124. (ORIGINAL) The therapeutic composition of any one of claims 113 to 120, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

125. (ORIGINAL) The therapeutic composition of any one of claims 113 to 120, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

126. (ORIGINAL) The therapeutic composition of any one of claims 113 to 120, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal

Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

127. (CANCELED) The use of an educated autologous, xenogeneic, syngeneic or non-autologous NKT cell in the manufacture of a therapeutic composition for modulating the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells, in a mammalian subject suffering of an immune-related or immune-mediated disorder or disease.

128. (CANCELED) The use of an educated autologous, xenogeneic, syngeneic or non-autologous NKT cell in the manufacture of a therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject, wherein educated NKT cells modulate the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells.

129. (CANCELED) The use of claim 127 or 128, wherein said educated NKT cells mediate an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

130. (CANCELED) The therapeutic composition of any one of claims 127 to 128 wherein the educated NKT cells of said composition modulate the Th1/Th2 cell balance towards pro-inflammatory cytokine producing cells in a mammalian subject suffering an immune-related or immune-mediated disorder or disease, and said NKT cells mediate a decrease in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

131. (CANCELED) The therapeutic composition of any one of claims 127 to 128 for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject, wherein the educated NKT cells of said composition modulate the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells.

132. (CANCELED) The use of an antibody that specifically recognizes the NKT cells, in the manufacture of a therapeutic composition for the manipulation of the NKT cells population in a mammalian subject suffering from an immune-related or immune-mediated disorder or disease.

133. (CANCELED) The use of claim 132, wherein said manipulation is the depletion of said NKT cell population.

134. (CANCELED) The use of claim 133, wherein depletion of said NKT cells population results in modulating the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells.

135. (CANCELED) The use of any one of claims 132 to 134, wherein said immune related disorder or disease is Non-Alcoholic Steatohepatitis.

136. (CANCELED) The use of any one of claims 132 to 134, wherein said immune related disorder or disease is diabetes mellitus or glucose intolerance.

137. (CANCELED) The use of any one of claims 132 to 134, wherein said immune-related or immune-mediated disorder or disease is obesity.

138. (CANCELED) The use of any one of claims 132 to 134, wherein said immune-related or immune-mediated disorder or disease is metabolic syndrome.

139. (CANCELED) The use of any one of claims 132 to 134, wherein said immune-related or immune-mediated disorder or disease is Graft Versus Host Disease.

140. (CANCELED) The use of any one of claims 132 to 134, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic

Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.

141. (CANCELED) The method of any one of claims 1 to 37 wherein said disease comprises colitis, Inflammatory Bowel Disease, Ulcerative Colitis, Crohn's Disease, Systemic Lupus, Osteoporosis, Non-Alcoholic Steatohepatitis, Diabetes Mellitus, glucose intolerance, obesity, metabolic syndrome, Graft Versus Host Disease, Multiple Sclerosis, Rheumatoid Arthritis, Eye Disease, Uvitis, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease, Vasculitis, Sclerderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, Myasthenia Gravis, non-HIV AIDS, (Systemic) Lupus Erythematosus, Juvenile Rheumatoid Arthritis, Idiopathic Thrombocytopenic Purpura, Scleroderma, Raynaud's Phenomenon, Mixed Connective Tissue Disorder, Celiac Disease, Crest Syndrome (Calcinosis Cutis, Raynaud's Phenomenon, Esophageal Dysfunction, Sclerodactyly and Telangiectasis), wound healing, or any other immune-related or immune-mediated disorder or disease.

142. (CANCELED) The method of any one of claims 81 to 110 wherein said disease comprises Inflammatory Bowel Disease, Ulcerative Colitis, Crohn's Disease, Systemic Lupus, Osteoporosis, Non-Alcoholic Steatohepatitis, Diabetes Mellitus, glucose intolerance, obesity, metabolic syndrome, Graft Versus Host Disease, Multiple Sclerosis, Rheumatoid Arthritis, Eye Disease, Uvitis, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease, Vasculitis, Scleroderma, CREST, Neurologic, Disease, Lung Disease, Myositis, Ear Disease, Myasthenia Gravis, non-HIV AIDS, (Systemic) Lupus Erythematosus, Juvenile Rheumatoid Arthritis, Idiopathic Thrombocytopenic Purpura, Scleroderma, Raynaud's Phenomenon, Mixed Connective Tissue Disorder, Celiac Disease, Crest Syndrome (Calcinosis Cutis, Raynaud's Phenomenon, Esophageal Dysfunction, Sclerodactyly and Telangiectasis), wound healing, or any other immune-related or immune-mediated disorder or disease.

143. (NEW) The method of claim 1, wherein said components comprise cellular immune reaction elements, humoral immune reaction elements and cytokines.

144. (NEW) The method of claim 2, wherein said components comprise cellular immune reaction elements, humoral immune reaction elements and cytokines.

145. (NEW) The method of claim 3, wherein said components comprise cellular immune reaction elements, humoral immune reaction elements and cytokines.

146. (NEW) The method of claim 6, further comprising the step of eliciting in said subject immune modulation of said immune-related or immune-mediated disorder or disease by administering to said subject components, cells, tissues and/or organs derived from any allogeneic donor suffering from said immune-related or immune-mediated disorder, xenogeneic sources, syngeneic sources, autologous sources, non-autologous sources, immunologically functional equivalents, or any combination thereof.

147. (NEW) The method of claim 7, further comprising the step of eliciting in said subject immune modulation of said immune-related or immune-mediated disorder or disease by administering to said subject components, cells, tissues and/or organs derived from any allogeneic donor suffering from said immune-related or immune-mediated disorder, xenogeneic sources, syngeneic sources, autologous sources, non-autologous sources, immunologically functional equivalents, or any combination thereof.

148. (NEW) The method of claim 6, further comprising eliciting in said subject up or down regulation of the immune response to said disorder or disease by oral tolerization, oral tolerance induction or oral immune regulation.

149. (NEW) The method of claim 7, further comprising eliciting in said subject up or down regulation of the immune response to said disorder or disease by oral tolerization, oral tolerance induction or oral immune regulation.

150. (NEW) The method of claim 6, further comprising immune modulation through oral tolerance induction or oral immune regulation.

151. (NEW) The method of claim 7, further comprising immune modulation through oral tolerance induction or oral immune regulation.

152. (NEW) A therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject comprising educated autologous, xenogenic, syngeneic or non-autologous NKT cells, said composition modulating the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells.

153. (NEW) The therapeutic composition of claim 152 wherein said educated NKT cells mediate an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

154. (NEW) The therapeutic composition of claim 152 wherein said educated NKT cells of said composition modulate the Th1/Th2 cell balance towards pro-inflammatory cytokine producing cells in a mammalian subject suffering an immune-related or immune-mediated disorder or disease, and said NKT cells mediate a decrease in the quantitative ratio between any one of IL4 and IL10 to IFNγ.

155. (NEW) A therapeutic composition for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject comprising an antibody that specifically recognizes NKT cells, and manipulates the NKT cell population in said mammalian subject.

156. (NEW) The therapeutic composition of claim 155 wherein said manipulation is the depletion of said NKT population.

157. (NEW) The therapeutic composition of claim 156 wherein the depletion of said NKT cell population results in modulation the Th1/Th2 cell balance toward pro-inflammatory cytokine producing cells.

158. (NEW) The therapeutic composition of claim 156 wherein the depletion of said NKT cell population results in modulating the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells.

159. (NEW) The therapeutic composition of claims 152 to 158 wherein said immune related disorder or disease is Non-Alcoholic Steatohepatitis.

160. (NEW) The therapeutic composition of claims 152 to 158 wherein said immune related disorder or disease is diabetes mellitus or glucose intolerance.

161. (NEW) The therapeutic composition of claims 152 to 158 wherein said immune related disorder or disease is obesity.

162. (NEW) The therapeutic composition of claims 152 to 158 wherein said immune related disorder or disease is metabolic syndrome.

163. (NEW) The therapeutic composition of claims 152 to 158 wherein said immune related disorder or disease Graft Versus Host Disease.

164. (NEW) The therapeutic composition of claims 152 to 158 wherein said immune related disorder or disease comprises the use of any one of claims 132 to 134, wherein said immune-related or immune-mediated disorder or disease comprises Osteoporosis, Multiple Sclerosis, SLE, Rheumatoid Arthritis, JRA, Eye Disease, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease (not including Diabetes), Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, or Myasthenia Gravis.